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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,793	12/26/2000	Ruedi H. Aebersold	P-IS 4534	3321

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EXAMINER

TRAN, MY-CHAU T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,793

Applicant(s)

AEBERSOLD ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 24-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-23, drawn to a method for identifying a polypeptide, classified in class 436, subclass 149.
 - II. Claims 24-43, drawn to a method for generating a polypeptide identification index, classified in class 436, subclass 173.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of group I and II are unrelated and independent inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different effects.

The feature of annotated polypeptide of group I is not required by the claims of the other group~~s~~. The feature of first and second polypeptide of group II is not required by the claims of the other group~~s~~.

3. During a telephone conversation with Deborah L. Cadena on 11/8/01 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-43

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

5. The information disclosure statement faxed on 11/30/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. It is noted the copies maybe lost in the mail.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. In claims 1 and 13, it is unclear what is meant by the term “a fragment of polypeptide.” Page 16, line 7-8 and page 17, lines 23-24 of the specification define the term “polypeptide” and “fragment,” respectively. A “polypeptide” is defined as two or more amino acids and a “fragment” is defined as any truncated form. Then a fragment polypeptide that is two amino acids would be an amino acid.
- b. The term “fragment mass” of claims 1 and 13 renders the claims indefinite since it does not particularly point out what the mass of the polypeptide is. Is the mass of the polypeptide less than 100 Da or greater than 100 Da?
- c. It is unclear what is meant by the term “annotated polypeptide index” of claims 1 and 13. Page 18, line 29-31 and page 19, lines 1-2 of the specification define this term but the definition is vague. It does not explain how or in what way is the polypeptide index being annotated.
- d. The term “optionally” of claim 2 (f) and 14 (g) is unclear if this step is included in the method or not.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 1-2 and 8-12 rejected under 35 U.S.C. 102(b) as being anticipated by Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999).

Yates, III and Link et al. disclose a method for identifying a polypeptide. The method includes a determining step of two or more characteristics (Yates, III: figure 3 and 4; pg. 7, right column, line 32-36; pg. 9, right column, line 10-62; and Link et al.: pg. 681, right column, line 4-29), a step that compare the characteristics, and identifying the polypeptide from an annotated polypeptide index (Yates, III: figure 3 and 4; pg. 7, right column, line 58-65; pg. 9, left column, line 52-60; and Link et al.: pg. 681, right column, line 4-29). The method further includes the step of determining one or more additional characteristics, the step of comparing the characteristics to an annotated polypeptide index, and repeating these steps (Link et al.: figure 2(c) and 3; pg. 681, right column, line 4-29 and pg 677, right column, line 44-52; and Yates, III: figure 3, 4, and 6).

These characteristics include polypeptide mass, amino acid composition, or order of elution on a chromatographic medium (Link et al.: figure 1 and 2(d); pg. 676, line 23-37; and Yates, III: figure 7; pg. 12, line 30-32 and continue to pg.13, line 1-2).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
13. Claims 3, 13-14, and 20-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Mann (*Nat. Biotechnol.*; 17(10):954-955; 1999) or Gygi et al. (*Nat. Biotechnol.*; 17(10):994-999; 1999).
- Yates, III and Link et al. references have been disclosed above which fail to explicitly disclose a method for identifying a polypeptide that include the step quantitating the amount of identified polypeptide. Mann and Gygi et al. teach a method of quantitating the amount of

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identified polypeptide (Mann: figure 1; and Gygi et al.: figure 2 and 4; pg.995, left column, line 1-8 and continue to right column, line 1-2).

It would have been obvious to one having ordinary skill in this art at the time the invention was made to include the method of quantitating the amount of identified polypeptide, as taught by Mann and Gygi et al., with Yates, III and Link et al. method of identifying the polypeptide in order to determine the relative quantities as well as the identity of the polypeptide in a single automated operation (pg 995, right column, line 1-2).

14. Claims 4-8 and 15-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Masselon et al. (*Anal. Chem.*; 72:1918-1924; 2000).

Yates, III and Link et al. references have been disclosed above which fail to explicitly disclose the method of increasing the accuracy of the mass measured. Masselon et al discloses the method of increasing the accuracy of the mass measured (pg 1923, right column, line 9-16).

It would have been obvious to one having ordinary skill in this art at the time the invention was made to include the method of increase the accuracy of the mass measured, as disclosed by Masselon et al, with Yates, III and Link et al. method of identifying the polypeptide in order to maintain the high confidence levels for polypeptide identification by the use of high-accuracy mass measurements (pg 1919, left column, line 12-13).

Masselon et al discloses the claimed invention except for the range of 100 ppm or greater. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the range of 100 ppm or greater, since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. The following prior arts teach a method of identifying a polypeptide:

- 1) Little et al. U.S. Patent 6,322,970 B1
- 2) Henzel et al. *Proc. Natl. Acad. Sci.*, 90:5011-5015, 1993
- 3) Yates III, *Electrophoresis*, 19:893-900, 1998
- 4) Jensen et al. *Proteins : Struct., Funct., Genet.*, Suppl. 2:74-89, 1998
- 5) Traini et al. *Electrophoresis*, 19:1941-1949, 1998
- 6) Erdjument-Bromage et al. *J. Chrom. A*, 826:167-181, 1998
- 7) Brockstedt et al. *J. Biol. Chem.*, 273(43):28057-28064, 1998

b. Leenheer et al. (*Mass Spectrom. Reviews*, 11: 249-307, 1992) disclose a method of quantitating the polypeptide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the

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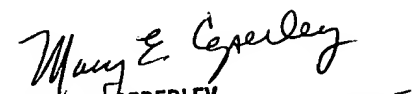
organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



mct

December 11, 2001


MARY E. CEPERLEY
PRIMARY EXAMINER *acting SPE*
ART UNIT ~~122~~1641